



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.       |
|--|-------------|----------------------|---------------------------------|------------------------|
| 10/563,681   | 06/21/2006  | Peter Schwind        | BPD-103US                       | 3643                   |
| 31344  | 7590        | 01/06/2010           |                                 |                        |
| RATNERPRESTIA<br>P.O. BOX 1596<br>WILMINGTON, DE 19899 |             |                      | EXAMINER<br>NGUYEN, BAO THUY L. |                        |
|  |             |                      | ART UNIT<br>1641                | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>01/06/2010         | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/563,681

**Applicant(s)**

SCHWIND ET AL.

**Examiner**

Bao-Thuy L. Nguyen

**Art Unit**

1641

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-15 is/are rejected.
- 7) ☒ Claim(s) 6 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment and arguments filed 17 September 2009 has been received.
2. Claims 1-24 are pending. Claims 4, 5, and 16-24 are withdrawn. Claims 1-3, 6-15 and 26 are under consideration.

### ***Withdrawn Rejections***

3. The rejection of claims 1-3 and 6-15 under 35 USC 112, first paragraph is withdrawn in view of the arguments. Supports for claim limitations may be found in paragraph [0051] and figures 3-6.
4. The rejection of claims 1-3 and 6-15 under 35 USC 112, second paragraph is withdrawn in view of the amendments to the claims.
5. The rejection of claims 1-3, 6, 7, 9 and 11-15 under 35 USC 103 as obvious over Geisberg in view of Jerome is withdrawn in view of the amendments to the claims and the argument. Geisberg in view of Jerome does not make obvious a device where erythrocyte serves as both the indicator particles and the analytes.
6. The rejection of claims 8 and 9 under 35 USC 103 as being unpatentable over Geisberg, Jerome and Eisinger is withdrawn in view of the amendments to the claims and the arguments.
7. The rejection of claims 1-3, 6-11 and 13-15 under 35 USC 103 as being unpatentable over Kang in view of Jerome and Eisinger is withdrawn in view of the amendments to the claims and the arguments. These references do not teach or make obvious a device where erythrocyte serves as both the indicator particle and the analytes.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-3 and 7-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/563,659 in view of Jerome (US 6,855,561).

‘659 teaches a device comprising an application zone, at least one group of at least two indicator zones, at least one absorption region and at least two different flow tracks are present.

‘659 differs from the instant claims in failing to teach particles comprising erythrocytes.

See the discussion of Jerome above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of ‘659 to include erythrocytes as the particles labels as taught by Jerome because Jerome teaches that erythrocytes labels are conventional and well known in the art.

This is a provisional obviousness-type double patenting rejection.

***Allowable Subject Matter***

10. The following is a statement of reasons for the indication of allowable subject matter: claims 1-3, 6-15 and 26 are allowable over the prior art of record because the prior art of record fail to teach or make obvious a device comprising a single membrane with an application zone, at least one absorption region, at least one group of at least two indicator zones located between the application zone and absorption regions, where the indicator zones are positioned on the membrane substantially parallel and absent a physical divider between them. The indicator zones comprise a first indicator zone containing a bonding element for binding the cellularly bound analyte and the at least two indicator zones comprise a second indicator zone containing a binding element for binding an analyte in the sample where the analyte is erythrocytes and serve as both the indicator particle and the analyte.
11. Claims 1-3, 6-15 and 26 would be allowed when a Terminal Disclaimer is received and approved.
12. Claims 6 and 26 are objected to as being dependent on a rejected claim.
13. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

**14. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**15.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
January 3, 2010